K094041

alpha orthopaedics

APR - 7 2010

510(k) Summary

Company Information:	Alpha Orthopaedics, Inc. 23575 Cabot Blvd., Ste. 210, Hayward, CA 94545
Contact Information:	Gina To Vice President, Regulatory/Quality Phone: (510) 783-5888; Fax: (510) 783-5889
Date Summary Prepared:	April 6, 2010
Trade Name:	Alpha Orthopaedics AT3™ System
Common Name:	Electrosurgical cutting and coagulation device and accessories
Classification:	Product Code GEI, Class II, CFR §878.4400
Predicate Devices (Legally Marketed Device):	• K090580 Thermage ThermaCool NXT System • K072849 Modification to Thermage ThermaCool System • K052778 Thermage ThermaCool Skin Marking Paper • K051710 Thermage ThermaCool Coupling Fluid • K013639 Thermage ThermaCool TC System

DEVICE DESCRIPTION

The AT3™ System delivers RF energy while cooling tissue by conduction. Components and accessories include the handpiece, handpiece with vibration, return pad, electronic footswitch (optional), cryogen canister, coupling fluid, skin marking paper, and treatment electrodes.

INTENDED USE

The radiofrequency-energy only delivery components of the Alpha Orthopaedics AT3 System are indicated for use in general surgical procedures for electrocoagulation and hemostasis.

The simultaneous application of radiofrequency energy and skin vibration by the Alpha Orthopaedics AT3 System is indicated for use in:

- General surgical procedures for electrocoagulation and hemostasis
- Relief of minor muscle aches and pain
- Relief of muscle spasms
- Temporary improvement of local circulation (i.e., blood circulation)

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the AT3 System are same as the Thermage ThermaCool NXT System.

SUBSTANTIAL EQUIVALENCE

The AT3 System that is the subject of this notification is substantially equivalent to the predicate legally marketed devices listed above.

SUMMARY OF PERFORMANCE TESTING

Performance, EMC, safety, and software testing have been completed.

CONCLUSION

The technological characteristics and the results of the performance data demonstrate that the Alpha Orthopaedics AT3 System is safe and effective and is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR - 7 2010

Alpha Orthopaedics, Inc.
% Ms. Gina To
23575 Cabot Boulevard, Suite 210
Hayward, CA 94545

Re: K094041
Trade/Device Name: Alpha Orthopaedics AT3™ System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulation Class: II
Product Code: GEI
Dated: April 6, 2010
Received: April 7, 2010

Dear Ms. To:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K094041

Device Name: Alpha Orthopaedics AT3™ System

Indications for Use:

The radiofrequency-energy only delivery components of the Alpha Orthopaedics AT3 System are indicated for use in general surgical procedures for electrocoagulation and hemostasis.

The simultaneous application of radiofrequency energy and skin vibration by the Alpha Orthopaedics AT3 System is indicated for use in:

- General surgical procedures for electrocoagulation and hemostasis
- Relief of minor muscle aches and pain
- Relief of muscle spasms
- Temporary improvement of local circulation (i.e., blood circulation)

Prescription Use __X__ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K094041